In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: September 25, 2024

SHIRLEY SCOTT,	*	
	*	Special Master Sanders
Petitioner,	*	
v.	*	No. 20-1982v
	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
	*	
Respondent.	*	

Jimmy A. Zgheib, Zgheib Sayad, P.C., White Plains, NY, for Petitioner.
Matthew Murphy, United States Department of Justice, Washington, DC, for Respondent.

RULING ON ENTITLEMENT[1]

On December 28, 2020, Shirley Scott ("Petitioner) filed a petition pursuant to the National Vaccine Injury Compensation Program.[2] Petitioner alleged that the administration of the influenza ("flu") vaccine she received on October 30, 2019, caused a right shoulder injury related to vaccine administration ("SIRVA"). Pet. at 1, ECF No. 1. Petitioner alleged her injury as a Table claim with a presumption of causation, and in the alternative, a causation-in-fact claim with a theory of causation. ECF No. 26 at 2.

After carefully analyzing and weighing all of the evidence presented in this case in accordance with the applicable legal standards,[3] I find that Petitioner has met her legal burden.

[1] Because this Ruling contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at https://www.govinfo.gov/app/collection/uscourts/national/cofc, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). **This means the Ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

[2] The Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-10 et seq. (hereinafter "Vaccine Act," "the Act," or "the Program"). Hereafter, individual section references will be to 42 U.S.C. § 300aa of the Act.

[3] While I have reviewed all of the information filed in this case, only those filings and records that are most relevant to the decision will be discussed. *Moriarty v. Sec'y of Health & Hum. Servs.*, 844 F.3d 1322, 1328 (Fed. Cir. 2016) ("We generally presume that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision.") (citation omitted); *see also Paterek v. Sec'y of Health & Hum. Servs.*, 527 F. App'x 875, 884 (Fed. Cir. 2013) ("Finding certain information not relevant does not lead to—and likely undermines—the conclusion that it was not considered.").

Petitioner has not provided preponderant evidence that she suffered from a SIRVA, but she has provided preponderant evidence that the flu vaccine she received on October 20, 2019, is the but-for cause of her right shoulder injury. Accordingly, Petitioner, is entitled to compensation.

I. Procedural History

The petition, filed on December 28, 2020, alleged that Petitioner suffered from a Table SIRVA as a result of a flu vaccination. Pet. at 1. On December 30, 2020, Petitioner filed seven exhibits, including vaccination records, medical records, and a declaration. *See* Petitioner's Exhibits ("Pet'r's Exs.") 1–7, ECF No. 6. Petitioner filed additional exhibits with updated medical records on November 16, 2021. Pet'r's Exs. 9–10, ECF No. 15. On May 17, 2022, Petitioner filed seven exhibits, including multiple declarations. Pet'r's Exs. 12–18, ECF No. 25. That same day, Petitioner filed a motion for a ruling on the record. Pet'r's Mot., ECF No. 26. I issued a scheduling order directing Respondent to respond to Petitioner's motion for a ruling on the record in his Rule 4(c) report. Sched. Order, issued on May 17, 2022. I also indicated that expert reports may be necessary before determining entitlement due to some evidence of a superior labrum[4] anterior to posterior ("SLAP") tear. *Id.*

On July 7, 2022, Respondent filed a Rule 4(c) report in which he recommended against compensating Petitioner for her alleged injury. *See* Respondent's Report ("Resp't's Report") at 1, ECF No. 27. Respondent averred that Petitioner failed to meet her burden to establish a Table SIRVA claim for three reasons: (1) Petitioner did not establish by preponderant evidence that her right shoulder pain began within 48 hours of vaccination; (2) Petitioner's pain was not limited to her right shoulder; and (3) Petitioner had a history of neuropathic pain, cervical radiculopathy, and degenerative disc disease which all reflect alternative causation to explain Petitioner's symptoms. *Id.* at 8–9. Respondent further argued that Petitioner failed to meet her burden to establish a causation-in-fact SIRVA claim because Petitioner did not establish that she suffered a specific shoulder injury and there was no expert report to articulate a medical theory in support of this claim. *Id.* at 9–10. Petitioner filed her reply to Respondent's response articulated in his Rule 4(c) report on July 13, 2022. Pet'r's Reply, ECF No. 28.

On August 16, 2022, I stayed Petitioner's motion for a ruling on the record to allow the parties to proceed with expert reporting. Sched. Order, ECF No. 31. Petitioner filed an expert report from Mark Bodor, M.D., accompanied by a curriculum vitae ("CV") and medical literature on September 23, 2022. Pet'r's Exs. 19–20, ECF No. 32. Respondent filed a responsive expert report from Geoffrey Adams, M.D., along with his CV and medical literature on January 19, 2023. Resp't's Exs. A–B, ECF No. 35. On February 22, 2023, Petitioner filed a supplemental expert report from Dr. Bodor with medical literature. Pet'r's Ex. 21, ECF No. 36.

I held a status conference on March 27, 2023, to discuss the evidence presented in this matter. Sched. Order, ECF No. 37; *see also* Min. Entry, docketed on Mar. 30, 2023. On April 13, 2023, Respondent filed a status report indicating his position that the filings in this matter were

[4] A SLAP tear occurs "when you tear cartilage in the inner part of your shoulder joint. The tears can be caused by injury or overuse and make it painful or difficult for you to move your shoulder and arm." *Cleveland Clinic* (July 26, 2024, 1:58pm), https://my.clevelandclinic.org/health/diseases/21717-slap-tear.

sufficient to decide Petitioner's Table claim on the record. Status Report, ECF No. 38. This matter is now ripe for a ruling on entitlement.

II. Summary of the Relevant Evidence

a. Medical Records

i. Vaccination

On October 30, 2019, Petitioner received an intramuscular flu vaccination in her right arm at Walmart Pharmacy in Flowood, Mississippi. Pet'r's Ex. 2 at 3–4, ECF No. 6-3.

ii. Post -Vaccination Medical History

On November 20, 2019, twenty-one days after vaccination, Petitioner saw her primary care physician ("PCP"), Dr. Tobe Momah, for an annual physical. Pet'r's Ex. 4 at 117–18, ECF No. 6-5. Petitioner reported "neck pain and spasm" after her flu vaccination, which limited her movement during exercise. *Id.* Dr. Momah prescribed diclofenac sodium 1% gel[5] for topical treatment of Petitioner's neck muscle spasm. *Id.* at 120.

On December 10, 2019, forty-one days after vaccination, Petitioner returned to her PCP and saw Dr. Ardarian Pierre with complaints of "right arm pain since receiving flu shot." *Id.* at 124. Petitioner reported that the symptoms began "4-5 weeks ago" and she found "some relief" with ice. *Id.* A physical examination showed a normal range of motion of Petitioner's right shoulder. *Id.* Dr. Pierre prescribed 750mg of Robaxin[6] and 800mg of Ibuprofen[7] and advised Petitioner to avoid exercise and weightlifting with her right arm until the symptoms resolved. *Id.* at 125.

On December 19, 2019, Petitioner returned to Dr. Momah with complaints of new onset "sharp pain in the right shoulder" after her flu vaccination. *Id.* at 129. Petitioner reported "decreased mobility, sharp pain and increased tenderness in the right shoulder." *Id.* Petitioner graded her pain as "10/10, worsening and sharp." *Id.* Petitioner noted that "she was in normal health" until the flu vaccination. *Id.* Petitioner further reported that the over-the-counter

[5] Diclofenac sodium 1% gel "is used to treat pain and other symptoms of arthritis of the joints . . . such as inflammation, swelling, stiffness, and joint pain." *Mayo Clinic* (July 26, 2024, 2:01pm), https://www.mayoclinic.org/drugs-supplements/diclofenac-topical-application-route/side-effects/drg-20063434?p=1.

[6] Robaxin is the "trademark for preparations of methocarbamol." *Robaxin*, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=44009 (last visited Sept. 16, 2024). Methocarbamol is a "skeletal muscle relaxant, administered orally, intramuscularly, or intravenously in the treatment of painful musculoskeletal conditions." *Methocarbamol*, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=30925 (last visited Sept. 16, 2024).

[7] Ibuprofen is "a nonsteroidal antiinflammatory drug derived from propionic acid and having also analgesic and antipyretic actions; administered orally in the treatment of pain, fever, dysmenorrhea, osteoarthritis, rheumatoid arthritis, and other rheumatic and nonrheumatic inflammatory disorders, and in the treatment and prophylaxis of vascular headaches." *Ibuprofen*, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=24560 (last visited Sept. 16, 2024).

medications, prescriptions, and ice did not resolve her pain. *Id.* A physical examination showed decreased range of motion in Petitioner's right shoulder and neck pain and stiffness. *Id.* at 130. Dr. Momah diagnosed Petitioner with neuropathic pain[8] of the right shoulder, acromioclavicular joint osteoarthritis[9], shoulder impingement[10], and cervical radiculopathy.[11] *Id.* at 131–32. Dr. Momah prescribed Petitioner 75mg of Lyrica[12] and 50mg of Ultram[13] and ordered x-rays of the right shoulder and cervical spine.[14] *Id.* at 133–34. Petitioner was also referred to physical therapy. *Id.* The cervical spine x-ray revealed "chronic degenerative disc changes [] most pronounced at C4-4, C5-6." *Id.* at 139. The right shoulder x-ray revealed "mild osteoarthritis" of the acromioclavicular[15] and glenohumeral joints.[16] *Id.* at 142.

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[8] Neuropathic pain, or neurogenic pain, is "pain, such as that occurring in causalgia or herpetic neuralgia, that results from direct stimulation of nervous tissue of the peripheral or central nervous system (except for sensitized C fibers), generally felt as burning or tingling and often occurring in an area of sensory loss." *Neurogenic Pain*, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=95722 (last visited Sept. 16, 2024).

[9] Osteoarthritis is "a noninflammatory degenerative joint disease seen mainly in older persons, characterized by degeneration of the articular cartilage, hypertrophy of bone at the margins, and changes in the synovial membrane. It is accompanied by pain, usually after prolonged activity, and stiffness, particularly in the morning or with inactivity." *Osteoarthritis*, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=35780 (last visited Sept. 16, 2024).

[10] Impingement is "advancement of one thing out of its expected place to where it may collide with something else." *Impingement*, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=24971 (last visited Sept. 16, 2024).

[11] Cervical radiculopathy is "radiculopathy of cervical nerve roots, often with neck or shoulder pain; compression of nerve roots is a common cause in this area." *Cervical Radiculopathy*, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=101392 (last visited Sept. 16, 2024).

[12] Lyrica is a "trademark for a preparation of pregabalin." *Lyrica*, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=29107 (last visited Sept. 16, 2024). Pregabalin is "a derivative of γ-aminobutyric acid (GABA) having anticonvulsant and antinociceptive effects, used in the treatment of neuropathic pain in diabetic neuropathy and postherpetic neuralgia; administered orally." *Pregabalin*, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=40751 (last visited Sept. 16, 2024).

[13] Ultram is a "trademark for a preparation of tramadol hydrochloride." *Ultram*, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=51748 (last visited Sept. 16, 2024). Tramadol hydrochloride is "an opioid analgesic used for the treatment of moderate to moderately severe pain following surgical procedures and oral surgery; administered orally." *Tramadol Hydrochloride*, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=50542 (last visited Sept. 16, 2024).

[14] The cervical spine is "the part of the spine comprising the cervical vertebrae." *Cervical Spine*, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=107685 (last visited Sept. 16, 2024). The cervical vertebrae are "the upper seven vertebrae, constituting the skeleton of the neck. Symbols C1 through C7." *Cervical Vertebrae*, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=117925 (last visited Sept. 16, 2024).

[15] The acromioclavicular joint is "the synovial joint between the acromion of the scapula and the acromial extremity of the clavicle." *Articulatio Acromioclavicularis*, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=59038 (last visited Sept. 16, 2024).

[16] The glenohumeral joint is "the joint formed by the head of the humerus and the glenoid fossa of the scapula." *Glenohumeral Joint*, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=83534 (last visited Sept. 16, 2024).

On December 27, 2019, Petitioner began physical therapy at the University of Mississippi Medical Center ("UMMC") for right shoulder pain with Stacey Lee, DPT. *Id.* at 145. During her initial evaluation, Petitioner reported pain since her flu shot which had worsened since onset. *Id.* Petitioner also noted that she "never had neck or shoulder issues prior to this onset." *Id.* Petitioner rated her current pain at 6.5/10. *Id.* A physical examination revealed range of motion restrictions with flexion[17] at 85 degrees, abduction[18] at 58 degrees, and external rotation[19] at 20 degrees with mild to moderate strength deficits. *Id.* at 147–48. By January 3, 2020, Petitioner completed three sessions of physical therapy. *Id.* at 161. At this session, Petitioner indicated that she desired to stop physical therapy until her orthopedic follow-up to discuss magnetic resonance imaging ("MRI") results. *Id.* at 162. Petitioner's reported pain was 2/10, and she was advised to continue with pain-free activities. *Id.*

On January 2, 2020, Petitioner underwent an MRI. *Id.* at 160. The impression was "[h]igh-grade near full-thickness articular[20] surface tear involving the majority of the supraspinatus tendon with tendinosis[21][,] [t]ear of the superior labrum [(SLAP)] [, and] [m]oderate AC joint osteoarthritis." *Id.*

On January 22, 2020, Petitioner returned to UMMC to see orthopedic surgeon Dr. William Geissler reporting right shoulder pain since her flu shot. *Id.* at 172. Petitioner noted that the pain was constant and "radiate[d] down to her elbow." *Id.* Petitioner also reported that the pain prevented her from sleeping. *Id.* Because of the pain, Petitioner could not "raise her arm in front of her and [could not] raise it behind" and "[felt] weak with overhead activities and some numbness." *Id.* A physical examination revealed flexion at 45 degrees, abduction of 45 degrees, and external rotation of 60 degrees *Id.* Dr. Geissler's impression was right torn rotator cuff[22] and

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[17] Flexion is "the act of bending or condition of being bent." *Flexion*, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=18796 (last visited Sept. 16, 2024).

[18] Abduction is "the act of abducting or state of being abducted." *Abduction*, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=101 (last visited Sept. 16, 2024). The abduction-external rotation test is performed when "the patient raises the arms to 180° above the shoulders, abducts them, bends the elbows, and opens and closes the fists for 3 minutes; reproduction of symptoms is a positive outcome." *Roos Test*, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=112908 (last visited Sept. 16, 2024).

[19] The external rotation method is "closed reduction of anterior shoulder dislocation by adducting the arm to the patient's side with the elbow flexed to 90 degrees as the patient lies supine, then rotating the arm externally using the forearm as a lever." *External Rotation Method*, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=89093 (last visited Sept. 16, 2024).

[20] Articular is "of or pertaining to a joint." *Articular*, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=4301 (last visited Sept. 16, 2024).

[21] Tendinosis or tendinitis is the "inflammation of tendons and of tendon-muscle attachments." *Tendinitis*, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=49150 (last visited Sept. 16, 2024).

[22] The rotator cuff is "a musculotendinous structure about the capsule of the shoulder joint, formed by the inserting fibers of the supraspinatus, infraspinatus, teres minor, and subscapularis muscles, blending with the capsule and providing mobility and strength to the shoulder joint." *Rotator Cuff*, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=67782 (last visited Sept. 16, 2024).

SLAP lesion. *Id.* Petitioner noted that physical therapy did not provide relief and requested surgery. *Id.*

Petitioner underwent arthroscopic debridement of the labrum and biceps tendon release of the right shoulder by Dr. Geissler on February 18, 2020. *Id.* at 800. Petitioner saw Dr. Geissler for a two-week post-operative visit on March 9, 2020. *Id.* at 220. A shoulder x-ray revealed a rotator cuff repair and subacromial decompression without complication. *Id.* at 217. Petitioner began post-operative physical therapy at UMMC on March 23, 2020. *Id.* at 223. Petitioner attended fifty-five sessions, through September 9, 2020. *Id.* at 561.

On July 13, 2020, Petitioner saw Dr. Geissler for a five-month post-operative visit. *Id.* at 360. Petitioner complained of a "frozen shoulder" with "pain about the shoulder that radiate[d] up about the base of the neck area, supraclavicular area" and "decreased motion." *Id.* A physical examination revealed range of motion restrictions with a flexion of 90 degrees and abduction of 90 degrees with mild strength deficits. *Id.* Dr. Geissler diagnosed Petitioner with adhesive capsulitis[23] and administered a Depo-Medrol[24] injection in her right shoulder. *Id.* Dr. Geissler further advised Petitioner to continue physical therapy. *Id.* Petitioner returned for a seven-month post-operative follow-up appointment on September 14, 2020. *Id.* at 576. Dr. Geissler found Petitioner made "absolutely no improvement" since her last visit and advised to proceed with a procedure. *Id.* at 577.

On September 22, 2020, Petitioner underwent an arthroscopic manipulation and debridement of adhesions and right shoulder decompression by Dr. Geissler. *Id.* at 801–02. During the procedure, Dr. Geissler noted that Petitioner's "shoulder was quite stiff. We could not manipulate it." *Id.* at 667. The procedure included "a total capsule release from the 3 o'clock position to the 9 o'clock position." *Id.* Petitioner began physical therapy at Elite Physical Therapy for post-operative rehabilitation on September 28, 2020. Pet'r's Ex. 5 at 131, ECF No. 6-6.

Petitioner returned to Dr. Geissler for a post-operative visit on September 30, 2020. Pet'r's Ex. 4 at 667. Petitioner was encouraged to use her shoulder as much as possible and to continue with physical therapy. *Id.* at 667–68.

On November 18, 2020, Petitioner saw Dr. Momah for concerns of high blood pressure and weight gain. *Id.* at 741. Petitioner noted that she was "unable to fully flex her right upper

[23] Adhesive capsulitis is "adhesive inflammation between the joint capsule and the peripheral articular cartilage of the shoulder with obliteration of the subdeltoid bursa, characterized by shoulder pain of gradual onset, with increasing pain, stiffness, and limitation of motion." *Adhesive Capsulitis*, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=62985 (last visited Sept. 16, 2024).

[24] Depo-Medrol is the "trademark for preparations of methylprednisolone acetate." *Depo-Medrol*, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=13281 (last visited Sept. 16, 2024). Methylprednisolone acetate is "the 21-acetate ester of methylprednisolone, administered topically as an antiinflammatory, by intramuscular injection in replacement therapy for adrenocortical insufficiency, and by intra-articular, intramuscular, intralesional, or soft-tissue injection as an antiinflammatory and immunosuppressant in a wide variety of disorders." *Methylprednisolone Acetate*, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=89217 (last visited Sept. 16, 2024).

extremity." *Id.* Petitioner was encouraged to use Voltaren[25] gel, to go to physical therapy, and to follow up with her orthopedic surgeon. *Id.*

Petitioner returned to Dr. Geissler for a post-operative visit on December 2, 2020. *Id.* at 767. Dr. Geissler noted that Petitioner "still need[ed] some additional therapy in motion, but she ha[d] improved significantly to what she was preoperatively." *Id.* Petitioner reported that she was "quite pleased and want[ed] to continue therapy" and no longer required pain medication. *Id.* A physical examination revealed active flexion of 120, abduction of 120, external rotation of 60, and strength 4/5. *Id.*

On February 2, 2021, Petitioner had her last visit for post-operative physical therapy. Pet'r's Ex. 8 at 7, ECF No. 11-2. Petitioner had a total of forty-nine visits. *Id.* Petitioner rated her pain at 2/10, met three of her goals, and partially met the remaining three goals. *Id.* at 7–8. Petitioner's progress plateaued and she was advised to continue exercises at home. *Id.*

Petitioner returned to Dr. Geissler for a post-operative visit on February 3, 2021. Pet'r's Ex. 9 at 14, ECF No. 15-2. Petitioner reported improvement with her physical therapy but requested additional pain medication. *Id.* A physical examination revealed flexion of 140 degrees, abduction of 140 degrees, external rotation of 60 degrees, and mild strength deficits. *Id.* Dr. Geissler prescribed Petitioner 50mg of Tramadol[26] and encouraged her to do home exercises. *Id.* at 14, 18.

On September 15, 2021, Petitioner returned to Dr. Geissler for a one-year post-operative visit. *Id.* at 32. Petitioner reported "some ache to her shoulder" and "a little bit of stiffness." *Id.* A physical examination revealed flexion at 140, abduction at 140, external rotation to 70, and strength at 4/5. *Id.* Dr. Geissler administered a 40mg injection of Depo-Medrol and advised Petitioner to return to physical therapy. *Id.*

Petitioner began an additional round of physical therapy at Elite Physical Therapy on September 20, 2021. Pet'r's Ex. 10 at 55, ECF No. 15-3. At her evaluation, Petitioner reported that she recently "had more pain and difficulty lifting arm overhead and behind back." *Id.* Petitioner reported pain of 5/10 with a flexion and abduction of 130. *Id.* at 55–56.

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[25] Voltaren is a "trademark for preparations of diclofenac sodium." *Voltaren*, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=53382 (last visited Sept. 16, 2024). Diclofenac sodium is "the sodium salt of diclofenac, administered orally in the treatment of rheumatoid arthritis, osteoarthritis, and ankylosing spondylitis and also for a variety of nonrheumatic inflammatory conditions." *Diclofenac Sodium*, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=69745 (last visited Sept. 16, 2024). "It is also applied topically to the conjunctiva to inhibit miosis during and to reduce ocular inflammation or photophobia after certain kinds of ophthalmic surgery and to the skin to treat actinic keratoses." *Id.*

[26] Tramadol hydrochloride is "an opioid analgesic used for the treatment of moderate to moderately severe pain following surgical procedures and oral surgery; administered orally." *Tramadol Hydrochloride*, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=50542 (last visited Sept. 16, 2024).

By November 4, 2021, Petitioner completed fifteen physical therapy sessions. *Id.* at 10. Petitioner's pain was 1/10 with active flexion of 165 and abduction of 160. *Id.* Petitioner had full strength. *Id.* at 10–11. Petitioner had met her long-term goals. *Id.* at 13.

On April 4, 2022, Petitioner returned to Dr. Geissler with complaints that her shoulder was "getting a little tight." Pet'r's Ex. 22 at 9, ECF No. 40-2. A physical examination revealed active flexion of 160, abduction of 140, and strength 4/5. *Id.* Dr. Geissler advised that Petitioner did not require further physical therapy because she had "good functional motion." *Id.* Petitioner was advised to continue at-home strengthening program. *Id.*

Petitioner returned to Dr. Geissler on March 6, 2024, for an evaluation after her shoulder "suddenly locked up" two weeks ago. *Id.* at 144. Petitioner reported that she had a stomach infection a few months ago and currently used a boot on her right foot. *Id.* at 144–45. A physical examination revealed active flexion of 140, abduction of 120, external rotation of 70, and strength at 4/5. *Id.* at 145. Dr. Geissler injected 4mg of Depo-Medrol into Petitioner's right shoulder and advised her to return in four months. *Id.* Dr. Geissler noted that Petitioner may require more than one injection and if "she [did] not improve, she may be a candidate for arthroscopic debridement of the calcium deposit." *Id.*

b. Petitioner's Declarations

On December 30, 2020, Petitioner filed a declaration, which was executed on December 28, 2020. Pet'r's Ex. 3 at 4, ECF NO. 6-4. Petitioner recalled that she received a flu vaccination in her dominant right shoulder on October 30, 2019. *Id.* at ¶ 3. Petitioner asserted that prior to the vaccine, she "had no pain, inflammation or dysfunction in [her] right shoulder." *Id.* Petitioner also noted that she had "never sustained any injury to her right shoulder other than the injuries resulting from the [vaccine]." *Id.*

Petitioner recalled that she felt "immediate pain at the injection site" and that the pharmacist advised her that her muscle flinched during the administration of the vaccine and that she would experience more soreness than usual for a few days. *Id.* at ¶ 4. Petitioner recalled that "the pain worsened over the next several days" and she felt pain with certain movements and a limited range of motion. *Id.* Petitioner managed her activities to limit her movement and managed the pain with heat, ice, and over-the-counter pain medications. *Id.*

On November 20, 2019, Petitioner saw Dr. Momah, her PCP, for an annual physical and reported the ongoing pain in her right shoulder and neck and the associated stiffness and spasms. *Id.* at ¶ 6. Petitioner received a topical cream prescription to apply to her right shoulder. *Id.*

On December 10, 2019, Petitioner saw Dr. Pierre for her persistent right shoulder pain because the topical cream had not resolved the pain. *Id.* at ¶ 7. Petitioner noted that Dr. Pierre advised Petitioner to hydrate and ice her shoulder three times a day and prescribed ibuprofen and flexeril.[27] *Id.*

[27] Flexeril is "trademark for a preparation of cyclobenzaprine hydrochloride." *Flexeril*, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=18790 (last visited Sept. 16,

Petitioner recalled returning to Dr. Momah on December 19, 2019, for a follow-up where she complained that the medications were not helping her injury. *Id.* Petitioner also noted worse right shoulder pain at night. *Id.* at ¶ 8. Petitioner received a prescription of Lyrica and Tramadol and a referral to physical therapy. *Id.* Petitioner began physical therapy in December 2019 and continued through January 2020. *Id.* at ¶ 9. Petitioner received an MRI of her right shoulder on January 2, 2020. *Id.* at ¶ 10.

On January 22, 2020, Petitioner recalled a right shoulder evaluation with orthopedist Dr. Geissler where he opined that the MRI showed a rotator cuff tear "around the same area where the flu show was administered" and recommended surgery. *Id.* at ¶ 11. Petitioner underwent right shoulder surgery on February 18, 2020, and was instructed to wear a sling. *Id.* at ¶ 12. By March 9, 2020, Petitioner returned for a post-operative visit with Dr. Geissler, who informed her that she could remove the sling and begin physical therapy. *Id.* at ¶ 13. Petitioner underwent eighteen sessions of physical therapy from March 23, 2020 through May 11, 2020. *Id.* at ¶ 14. Petitioner also recalled that she was given exercises to do at home, which she did twice per day. *Id.* Petitioner noted that she worked "very hard to get back to normal" but her "shoulder was still very painful." *Id.*

After a May 11, 2020 follow-up with Dr. Geissler, Petitioner was ordered to continue physical therapy. *Id.* at ¶ 15. Petitioner underwent twenty-five physical therapy sessions from May 13, 2020 through July 10, 2020 and "had excruciating pain after each session" such that nothing had hurt "so bad in [her] life." *Id.* at ¶ 16. Petitioner recalled that the physical therapy provider indicated that this was a "frozen shoulder." *Id.* Petitioner stated that this was "a terrible feeling of pain and [she] would often cry on [her] way back home from therapy." *Id.* Petitioner continued to ice her shoulder at night and struggled to sleep because of the pain, only able to sleep when "propped up in bed." *Id.*

On July 13, 2020, Petitioner recalled another follow-up with Dr. Geissler where she reported the severe pain and frozen shoulder. *Id.* at ¶ 17. Dr. Geissler administered a steroid injection in Petitioner's shoulder and ordered additional physical therapy. *Id.* Dr. Geissler advised Petitioner that if her shoulder did not improve, she may require an additional surgery to remove scar tissue. *Id.* at ¶¶ 17–18. Petitioner underwent eleven physical therapy sessions from July 14, 2020 through September 9, 2020, where she "did not notice any improvement in [her] range of motion," and she "continued to have pain and functional limitations." *Id.* at ¶ 18.

Petitioner recalled a vacation where she was "unable to enjoy any recreational activities, such as tennis or jet skiing, because of [her] right shoulder pain and dysfunction." *Id.* Petitioner added that she was an "active person" and the injury from the vaccination prevented her from enjoying many hobbies. *Id.*

2024). Cyclobenzaprine hydrochloride is "a compound structurally related to the tricyclic antidepressants, used as a skeletal muscle relaxant for relief of painful muscle spasms; administered orally." *Cyclobenzaprine Hydrochloride*, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=12135 (last visited Sept. 16, 2024).

On July 23, 2020, Petitioner had a visit with her PCP for high blood pressure with a measurement of 179/96. *Id.* at ¶ 19. Petitioner received a prescription of cream and ibuprofen for her right shoulder pain. *Id.*

Petitioner stated that on August 24, 2020, she turned down a "principal position at the Mississippi Department of Correctional Center" due to her shoulder injury and the extensive requirement for physical therapy and an additional surgery. *Id.* at ¶ 20.

Petitioner recalled a follow-up with Dr. Geissler on September 14, 2020, where "[a]fter trying to move [her] arm, he immediately said [Petitioner] had frozen shoulder" and needed surgery. *Id.* at ¶ 21. Petitioner underwent right shoulder surgery on September 22, 2020. *Id.* at ¶ 22. Petitioner began physical therapy on September 28, 2020. *Id.* at ¶ 23. She stated that "[a]lthough [she was] doing better with therapy, [she] still ha[d] weakness [and] limited range of motion in [her] right shoulder." *Id.* Petitioner noted that through December of 2020, she "continue[s] to attend physical therapy to this day." *Id.*

On September 30, 2020, Petitioner recalled a follow-up with Dr. Geissler where he advised her to continue physical therapy and use her shoulder as much as possible. *Id.* at ¶ 24. On November 18, 2020, Petitioner recalled an appointment with Dr. Momah for high blood pressure where he recommended continued use of the pain cream. *Id.* at ¶ 25. On December 2, 2020, Petitioner had a follow-up with Dr. Geissler where he prescribed six additional weeks of physical therapy. *Id.* at ¶ 26.

Petitioner summarized her condition as follows:

> I continue [to] have pain, limitations[,] and dysfunction in my right shoulder to this day. Although my symptoms are improved, I continue to have weakness and limited range of motion in my right shoulder. I still feel pain and tightness in my shoulder with activities, and I continue to manage the pain with oxycodone when it gets bad. I still have high blood pressure which I believe is related to my shoulder injury. My quality of life has been significantly affected because this injury is to my dominant right shoulder. I still have difficulty with activities of daily living involving the use of my dominant right arm. I am still unable to enjoy recreational activities because of my right shoulder pain and dysfunction. I still have nighttime pain and difficulty sleeping due to the pain. I developed high blood pressure due to my shoulder injury and the pain medications I had to take, and I am now taking two blood pressure pills per day. I have come to the conclusion that even though I work very hard doing exercise at home and attending physical therapy, my right shoulder will never be the same as it was prior to the vaccination. As a result of my shoulder injury. I feel that I will never be able to do the things I was able to do prior to the vaccination.

Id. at ¶ 27. Petitioner added that she suffered "residual effects from [her] right shoulder injury for more than six months after the October 30, 2019 vaccination." *Id.* at ¶ 28.

On May 17, 2022, Petitioner filed a supplemental declaration with additional details, which was executed on May 11, 2022. Pet'r's Ex. 12 at 3, ECF No. 25-2. Petitioner added that the

administering pharmacist of the vaccination at issue told her that "her muscle jumped" during vaccination, which was going to cause more pain than usual. *Id.* at ¶ 3. Petitioner noted that she has a high pain tolerance and "tried to bear through it" but the pain continued to worsen. *Id.* Petitioner "returned to the pharmacy and spoke with the administering pharmacist several times over the next few weeks" and informed him that the pain was worsening. *Id.* The pharmacist recommended ice and advised that it could take up to four weeks to subside. *Id.* Petitioner added that she trusted him and had no reason to believe otherwise, noting that she "knew nothing about SIRVA" and never was informed that she should see a doctor if the pain persisted. *Id.* Petitioner recalled attempting to manage the pain with heat, ice, and Tylenol but it continued to worsen. *Id.* Petitioner was "guarding [her] shoulder and holding [her] right arm up and against [her] body to avoid the pain" which caused her right arm to appear shorter than her left and the pain crept from her right shoulder into the right side of her neck. *Id.*

Petitioner added that she has had "severe pain in her right shoulder" since the vaccination at issue. *Id.* at ¶ 7. She wrote that her diagnoses include "rotator cuff tear, tendinosis, impingement syndrome, and adhesive capsulitis, all caused by the vaccination." *Id.* Petitioner recalled that she has attended 121 physical therapy sessions and underwent two surgeries. *Id.* Petitioner noted that after her first surgery on February 18, 2020, she struggled living alone and maintaining household chores to such a degree that she bought a train ticket for her sister from Chicago, Illinois to come stay with her and assist during her recovery. *Id.* at ¶ 8.

Petitioner recalled that she paused her physical therapy sessions from February 4, 2021 through September 14, 2021, instead opting to perform the exercises at home, because she had utilized half of the Medicare-covered physical therapy sessions and wished to spread them out over her recovery. *Id.* at ¶ 9. Petitioner purchased a YMCA membership to continue water therapy and shoulder exercises at the gym. *Id.* Petitioner returned to physical therapy from September 14, 2021 through November 4, 2021. *Id.* at ¶ 10. Upon discharge, Petitioner continued to do exercises on her own at the YMCA. *Id.*

Petitioner noted that as of December of 2020, she continues to have "severe pain in [her] right shoulder to this day" and feels that it will never be the same. *Id.* at ¶ 11. Driving long distances causes Petitioner's shoulder to be stiff and painful. *Id.* Petitioner stated that she "will never be able to do simple things which [she] was previously able to do, such as washing [her] back by [herself]" and that she misses restful nights of sleep. *Id.* Petitioner added that she "had to learn to live [with her] shoulder limitations by modifying the way [she does] things and avoiding certain activities that [] will cause increased pain." *Id.*

c. Declaration of Anne Hanson

On May 17, 2022, Petitioner filed a declaration by Anne Hanson, which was executed on May 10, 2022. Pet'r's Ex. 13 at 1, ECF No. 25-3. Ms. Hanson stated that she is a water fitness instructor and that Petitioner has attended her class for several years. *Id.* at ¶¶ 1–2. Ms. Hanson noted that as an instructor, she "pay[s] close attention to the physical limitations and impairments of every one of her clients." *Id.* at ¶ 1.

Ms. Hanson recalled that on or about November 2019, she noticed that Petitioner "was holding her right arm stiffly by her side, which was unlike her." *Id.* at ¶ 3. Upon questioning, Petitioner advised Ms. Hanson that "she recently received a flu shot in her right shoulder and she had been having worsening pain ever since." *Id.* The following day, during a weight-lifting water fitness class, Ms. Hanson recalled that Petitioner could not lift a 1.8 lb. weight with her right arm and that her arm was very flushed and hot to the touch. *Id.* at ¶ 4. Ms. Hanson noted that she advised Petitioner to avoid lifting any weight with her right arm until she saw a doctor. *Id.* Ms. Hanson added that since that time, Petitioner has missed water fitness classes. *Id.* at 5. The COVID-19 pandemic closed the in-person water fitness classes shortly thereafter. *Id.*

d. Declaration of Mario Wiggins

On May 17, 2022, Petitioner filed a declaration by Mario Wiggins, which was executed on May 10, 2022. Pet'r's Ex. 14 at 1, ECF No. 25-4. Mr. Wiggins stated that he is an online exercise coach and has worked with Petitioner since 2017. *Id.* at ¶¶ 1–2. He recalled that on or about November 7, 2019, Petitioner informed him of pain in her right shoulder that began "as soreness after she received a flu shot about one week prior, and that it never got better and instead had been getting worse ever since." *Id.* at ¶ 3. Mr. Wiggins added that he noticed Petitioner had a significantly decreased range of motion in her right shoulder. *Id.* Mr. Wiggins further stated that Petitioner "had right shoulder pain ever since," including "limited range of motion" and "noticeable dysfunction and limitations in her right shoulder." *Id.* Mr. Wiggins noted that Petitioner "has not been able to do regular exercises ever since." *Id.* at ¶ 4.

e. Declaration of Judy Hetzel

On May 17, 2022, Petitioner filed a declaration by Judy Hetzel, which was executed on May 11, 2022. Pet'r's Ex. 15 at 1, ECF No. 25-5. Ms. Hetzel stated that she is a long-time friend of Petitioner and sees her at least two times per month, in addition to seeing each other a few times a month in water aerobics class. *Id.* at ¶ 1. Ms. Hetzel recalled that on or about November 2019 before Thanksgiving, during a water aerobics class, Petitioner informed her "that she had pain in her right shoulder since receiving a flu shot a few weeks prior" and that the "pain was getting worse." *Id.* at ¶ 2. Ms. Hetzel noticed that Petitioner's "right shoulder function has been impaired since that time." *Id.*

Ms. Hetzel noted that prior to this vaccination, Petitioner "was always very active" and she "always participated fully in all water aerobics classes." *Id.* at ¶ 3. Ms. Hetzel added that since the injury, Petitioner has not been able to use her right arm. *Id.* Ms. Hetzel stated that "[t]o this day, [Petitioner] still has discomfort in her right arm and she still has limited range of motion in her right shoulder." *Id.* at ¶ 4.

f. Declaration of Jearldine White

On May 17, 2022, Petitioner filed a declaration by Jearldine White, which was executed on May 12, 2022. Pet'r's Ex. 16 at 2, ECF No. 25-6. Ms. White stated that she is a long-time, close friend of Petitioner and they talk on the phone almost every day. *Id.* at ¶ 1. Ms. White recalled that prior to October 30, 2019, Petitioner "never complained to me about pain in her right shoulder"

and that "she was generally in good health and had no issues with her right shoulder." *Id.* at ¶ 2. Ms. White recalled speaking with Petitioner on the phone on October 29, 2019, when Petitioner stated that she was going to get her flu vaccination the following day. *Id.* The next day, Ms. White recalled speaking to Petitioner on the phone, when Petitioner stated that she got her vaccination at Walmart Pharmacy in her right shoulder and "that she felt more sore than usual." *Id.* at ¶ 3. Ms. White further recalled Petitioner stating that "her muscle jumped" and that the administering pharmacist advised that "the pain might last a few days but will eventually go away on its own." *Id.*

Ms. White recalled that Petitioner's pain continued to worsen and that she returned to the pharmacy multiple times, where the pharmacist advised "that the pain would eventually go away on its own, but that it can take up to four to six weeks to get better." *Id.* at ¶ 4. Ms. White noted that Petitioner's pain continued to worsen, and she decided to see a doctor. *Id.*

Ms. White added that Petitioner has undergone two surgeries on her right shoulder and that the physical therapy following the first surgery "made her pain worse." *Id.* at ¶ 5. Ms. White noted that Petitioner often called her crying after her physical therapy sessions "because she was in so much pain" and that she developed frozen shoulder and her "shoulder locked up" which required a second surgery. *Id.* Ms. White stated that Petitioner "still has limited range of motion in her right shoulder" and while "her pain seems more manageable now, she is still not the same after this injury." *Id.* at ¶ 6.

g. Declaration of Abraham Scott

On May 17, 2022, Petitioner filed a declaration by Abraham Scott, which was executed on May 11, 2022. Pet'r's Ex. 17 at 2, ECF No. 25-7. Mr. Scott stated that he has lived with and been married to Petitioner for approximately 30 years. *Id.* at ¶ 1. Mr. Scott recalled that Petitioner woke up on October 31, 2019, the day after her vaccination, complaining that "she could hardly move or raise her right arm" and that "her muscle jumped when she was given the vaccine." *Id.* at ¶ 3. Over the next few days, Mr. Scott observed Petitioner's pain worsening to the point where "she had no movement in her right shoulder and arm" and she "held her arm close to her body and was afraid to move it because of the pain." *Id.* at ¶ 4.

Mr. Scott added that Petitioner "has been through a lot because of this injury to her dominant right arm" including two surgeries and extensive physical therapy. *Id.* at ¶ 5. For a while, Petitioner "had no movement in her arm," and she could not assist with household chores. *Id.* Mr. Scott noted that to date, May 11, 2022, Petitioner continued to have pain in her right shoulder and could not "lift items of weight or reach overhead or across her body with her right arm." *Id.* Additionally, Petitioner could not drive long distances and struggled to sleep. *Id.* at ¶ 6. Mr. Scott concluded that Petitioner "has learned to adapt and live with her shoulder limitations." *Id.*

h. Expert Review

i. Expert Backgrounds

1. Petitioner's Expert, Marko Bodor, M.D.

Dr. Bodor received his medical degree from the University of Cincinnati Medical School in 1987. Pet'r's Ex. 20 at 1, ECF No. 32-8. Dr. Bodor then completed an internship in surgery at the University of California, San Diego in 1988. *Id.* Next, Dr. Bodor completed residency in physical medicine and rehabilitation at the University of Michigan in 1993. *Id.*

Dr. Bodor is board-certified in physical medicine and rehabilitation, sports medicine, and pain medicine. Pet'r's Ex. 19 at 1, ECF No. 32-2. Dr. Bodor was "the first to describe vaccination-related shoulder dysfunction and its disease mechanism" in the Journal of Vaccine. *Id.* Since 2007, Dr. Bodor has "treated or consulted on approximately 50 patients with [vaccine-related shoulder dysfunction], 30 of which [were] in the last 5 years." *Id.*

Since 1995, Dr. Bodor has been in private practice as an interventional physiatrist. Pet'r's Ex. 20 at 1. Dr. Bodor also serves as Medical Director of the Synergy Medical Fitness/Wellness Center, Queen of the Valley Medical Center, and Napa Medical Research Foundation. *Id.* at 2.

2. Respondent's Expert, Geoffrey Abrams, M.D.

Dr. Abrams received his medical degree from the University of California, San Diego in 2007. Resp't's Ex. B at 1, ECF No. 35-12. Dr. Abrams then completed a surgical internship in 2008 and residency in orthopedic surgery in 2012 at Stanford University Hospital and Clinics. *Id.* Dr. Abrams also completed a fellowship in orthopedic sports medicine at Rush University Medical Center. *Id.*

Dr. Abrams is a board-certified orthopedic surgeon with a subspeciality certification in sports medicine. Resp't's Ex. A at 1, ECF No. 35-1. Dr. Abrams currently serves as an Assistant Professor of Orthopedic Surgery, the Director of Sports Medicine for Varsity Athletics, and Director of the Lacob Family Sports Medicine Center at Stanford University. *Id.* Dr. Abrams also serves as "Team Physician for numerous professional and collegiate sports teams in the San Francisco Bay Area." *Id.*

Additionally, Dr. Abrams has a "surgical practice focused on orthopedic conditions of the shoulder" and has "published extensively on the shoulder and other musculoskeletal pathology, with over 120 total peer-reviewed publications." *Id.*

ii. Expert Reports

1. Dr. Bodor's Expert Report

Petitioner filed Dr. Bodor's expert report on September 23, 2022. Pet'r's Ex. 19. Dr. Bodor presented his medical theory and opined that Petitioner's shoulder pain:

> [S]tems from a chain reaction which started with a flu vaccination that likely penetrated through the deltoid muscles and into her rotator cuff and shoulder capsule, triggering an immune-mediated attack on these structures, essentially a

> focal autoimmune response, consisting of progressively increasing inflammation and eventually adhesive capsulitis.

Id. at 5. Dr. Bodor further explained that Petitioner's arthroscopic surgery "appeared to have resolved much of her pain, by possibly 'washing out' vaccine from where it was deposited in the cuff and capsule[.]" *Id.* Dr. Bodor continued that, over time, Petitioner "experienced a recurrence of scarring and adhesions, possibly on the basis of familial genetic predisposition, requiring a second operation which did not completely resolve her pain and functional deficits." *Id.*

Dr. Bodor also analyzed the medical records and timeline for Petitioner's injury. Dr. Bodor stated that his analysis of the medical record "indicate[d] that [Petitioner] did suffer from both right shoulder and neck pain from the outset and time of her flu vaccination." *Id.* at 4. Dr. Bodor addressed a contradiction in a medical record from Dr. Momah on November 20, 2019, where the review of systems stated, "negative for back pain, neck pain, and neck stiffness" while the narrative record itself stated "neck pain and spasm post-flu shot[.]" *Id.* (citing Pet'r's Ex. 4 at 117–18). Dr. Bodor opined that this failure to include the neck pain and stiffness in the review of systems was an oversight by Dr. Momah and does not change his opinion that Petitioner's onset of pain was immediately after the vaccination, which satisfies the temporal requirement in this matter. *Id.* at 4. Dr. Bodor also noted that "pain in neck" along the trapezius "is frequently experienced in conjunction with shoulder problems" because of "trapezius muscle overuse secondary to increased rotation of the scapula to compensate for reduced movement at the glenohumeral joint because of pain or injury [at that] joint." *Id.*

Dr. Bodor next disputed Dr. Momah's radiculopathy diagnosis given to Petitioner on December 19, 2019. *Id.* (citing Pet'r's Ex. 4 at 129). Dr. Bodor noted that Dr. Momah is a general primary care provider, not a specialist, and that Petitioner was never diagnosed with radiculopathy by any of her subsequent musculoskeletal specialists, including her physical therapist and orthopedic surgeon. *Id.* Dr. Bodor also cited Petitioner's symptoms, stating that her lack of "complaints of numbness or tingling down the arm to the fingers" does not support a radiculopathy diagnosis. *Id.* Additionally, if Petitioner solely suffered from radiculopathy, it would not explain her limited passive range of motion in her right shoulder. *Id.* at 4–5. Dr. Bodor opined that the above evidence supports a shoulder injury, rather than a radiculopathy. *Id.*

Dr. Bodor also pointed to Petitioner's "markedly reduced passive shoulder range of motion" by December 27, 2019, which indicated that "adhesive capsulitis had set in." *Id.* at 5 (citing Pet'r's Ex. 4 at 145). Dr. Bodor defined adhesive capsulitis as "white cell infiltration into the capsule of the joint, which is similar to what has been noted histologically in cases of vaccination-related shoulder dysfunction at time of surgery." *Id.* Dr. Bodor elaborated that "[v]accine inadvertently injected into the rotator cuff or shoulder capsule result[ed] in an immune-mediated inflammatory reaction" and cited a recent paper by Hirsiger et al.,[28] which described "unique auto-antibodies in patients with vaccination-related shoulder dysfunction . . . [which were] not present in controls who received the same vaccinations and did not have these problems." *Id.* (citing Pet'r's Ex. 19, Tab 5, ECF No. 32-7).

[28] Julia R. Hirsiger et al., *Chronic Inflammation and Extracellular Matrix-Specific Autoimmunity Following Inadvertent Periarticular Influenza Vaccination*, 124 J. AUTOIMMUNITY 102714 (2021).

2. Dr. Abrams' Expert Report

Respondent filed Dr. Abrams' expert report on January 19, 2023. Resp't's Ex. A. Dr. Abrams opined that Petitioner's "symptoms are not consistent with SIRVA" because she did not experience "frozen shoulder symptoms of pain and stiffness" immediately after the vaccination. *Id.* at 4. Dr. Abrams pointed to Petitioner's two primary care visits within a month and a half post vaccination to support this contention. *Id.* Dr. Abrams stated that Petitioner failed to report "direct shoulder area pain[,]" instead complaining of "neck pain and spasm which limit[ed] her movement" during her visit on November 20, 2019. *Id.* (citing Pet'r's Ex. 4 at 117). Dr. Abrams also noted that Petitioner received a shingles vaccination during this visit. *Id.* Dr. Abrams further referred to Petitioner's primary care visit on December 10, 2019, where there is documentation of "right arm pain" but a "normal range of motion of the shoulder" upon physical examination. *Id.* (citing Pet'r's Ex. 4 at 124).

Dr. Abrams then explained SIRVA generally. *Id.* Dr. Abrams wrote that "SIRVA involves an inflammatory reaction with the shoulder from injected antigenic material within the vaccine, with the most common manifestations of SIRVA being frozen shoulder." *Id.* Dr. Abrams continued that if SIRVA had been related to Petitioner's shoulder pain, there would have been "decreased motion of the shoulder shortly after the vaccination – and certainly before the . . . visit on December 10, 2019[,] in which Petitioner's range of motion was documented to be 'normal.'" *Id.* (citing Pet'r's Ex. 4 at 124). Dr. Abrams added that while "automated errors and omissions in the medical record are always possible," it is likely that a shoulder examination for shoulder pain would be documented correctly. *Id.* at 4–5.

Next, Dr. Abrams proposed two explanations for Petitioner's shoulder pain: (1) de novo adhesive capsulitis, or frozen shoulder, or (2) rotator cuff and other structural abnormalities. *Id.* at 5. Dr. Abrams stated that "adhesive capsulitis that arises outside of any SIRVA event[] is one of the most common causes of shoulder pain in middle-aged females." *Id.* Dr. Abrams added that Petitioner "has 'very high' levels of LDL and total cholesterol [], and this is associated with an increased risk of frozen shoulder." *Id.* (citing Pet'r's Ex. 4 at 122). Further, the "key to determination [of] whether frozen shoulder is associated with SIRVA is the proximity of the shoulder pain and stiffness to the vaccination" which Petitioner lacks in this case. *Id.* Regarding the second explanation, Dr. Abrams pointed to Petitioner's MRI from January 2020 as supportive evidence of a rotator cuff tear and "other structural abnormalities." *Id.* (citing Pet'r's Ex. 4 at 160). Dr. Abrams added that the structural abnormalities could not be caused by the vaccination because there was no "edema[29] in the rotator cuff (or adjacent bone) nor significant bursitis from an inflammatory response that would indicate injections of the vaccine into the subacromial space or adjacent tissues." *Id.*

[29] Edema is "the presence of abnormally large amounts of fluid in the intercellular tissue spaces of the body, usually referring to subcutaneous tissues. It may be localized (as from venous obstruction, lymphatic obstruction, or increased vascular permeability) or systemic (as from heart failure or renal disease)." *Edema*, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=15589 (last visited Sept. 16, 2024).

Lastly, Dr. Abrams addressed Dr. Bodor's discussion of the Gorski and Schwartz[30] article and proposal of "the phenomenon of how neck pain may be caused by shoulder pathology . . . to explain [Petitioner's] initial neck area symptoms[.]" *Id.* (citing Pet'r's Ex. 19, Tab 3, ECF No. 32-5). Dr. Abrams disputed this conclusion, stating that the "patients in the Gorski [and Schwartz] study included patients with pain in the 'superior-medial border of the scapula' which is actually part of the back (not the neck itself)[,]" had a significantly younger average age than Petitioner, and did not have "documented cervical spine pathology[.]" *Id.* For these reasons, Dr. Abrams asserted that the Gorski and Schwartz literature does not support Petitioner's claim that the vaccination was responsible for her musculoskeletal complaints. *Id.*

Dr. Abrams concluded with a summary of his opinion:

> The onset of shoulder range of motion deficits at nearly two months after the vaccination in question make SIRVA an unlikely diagnosis in this particular case. In addition, frozen shoulder not related to SIRVA as well as the underlying structural abnormalities of [] [P]etitioner's shoulder provide more likely explanations for her symptoms.

Id. at 6.

3. Dr. Bodor's Supplemental Expert Report

Petitioner submitted a supplemental expert report from Dr. Bodor on February 22, 2023. Pet'r's Ex. 21, ECF No. 36-2. Dr. Bodor opined that:

> [T]he sequence of events and process leading to adhesive capsulitis related to SIRVA might start immediately following a vaccination, it has been [his] experience that it does not fully manifest, with marked reductions of active and passive range of motion, until 3 to 6 weeks later.

Id. at 1. Dr. Bodor added that the above opinion is based upon his experience "with over 50 cases for the [Program] and 25 seen in [his] practice in the last 15 years." *Id.* In Petitioner's case, "her shoulder range of motion was, at the latest, reduced by 12/19/19, which would have been 39 days (5 weeks and 4 days) after her vaccination" which is "well within the window of adhesive capsulitis related to SIRVA)." *Id.* (citing Pet'r's Ex. 4 at 130–31).

Dr. Bodor next addressed Petitioner's high cholesterol, noting that "it may have been a contributing factor" but the timing and onset of symptoms is "consistent with the vaccination being the primary trigger and cause of [Petitioner's] adhesive capsulitis." *Id.* Additionally, Dr. Bodor noted that Petitioner's onset within 48 hours of vaccination is supported by five witness affidavits. *Id.* (citing Pet'r's Exs. 13–17).

Dr. Bodor further discussed Petitioner's neck pain. *Id.* Dr. Bodor stated that Dr. Momah's description of Petitioner's neck pain is consistent with a shoulder problem, as described by Gorski

[30] Jerrold M. Gorski & Lawrence H. Schwartz, *Shoulder Impingement Presenting as Neck Pain*, 4 J. BONE & JOINT SURGERY 635 (2003).

and Schwartz. *Id.* (citing Pet'r's Ex. 19, Tab 3). Dr. Bodor opined that while "pain described along the border of the medial scapula is actually in the upper back or thoracic spine[,]" lay people and Dr. Gorski describe this pain as part of the "neck." *Id.* Dr. Bodor continued that this fact makes it just as likely that Petitioner and Dr. Momah described the symptoms as "neck pain" while it was actually stemming from Petitioner's shoulder. *Id.* (citing Pet'r's Ex. 4 at 117). Dr. Bodor also pointed to subsequent reports that Petitioner suffered from shoulder pain and loss of range of motion. *Id.*

Finally, Dr. Bodor addressed Petitioner's radiographs, which Dr. Abrams stated showed evidence of cervical spine degenerative disc disease. *Id.* at 2 (citing Pet'r's Ex. 4 at 139). Dr. Bodor opined that while Petitioner's pain could have been caused by her neck, cervical spine degenerative disc disease did not account for Petitioner's loss of passive range of shoulder motion, which is "specific to either adhesive capsulitis or osteoarthritis[.]" *Id.* (citing Pet'r's Ex. 4 at 147–49). Dr. Bodor continued that Petitioner could not have osteoarthritis because of the MRI results. *Id.* (citing Pet'r's Ex. 4 at 160).

Dr. Bodor concluded his report with a summary of his opinion:

> [Petitioner's] ongoing shoulder pain stems from a sequence of events which started with a flu vaccination and led to adhesive capsulitis. Her arthroscopic surgery initially helped, but then over time she experienced a recurrence of scarring and adhesions, requiring a second operation which did not completely resolve her pain and functional deficits.

Id.

III. Ruling on the Record

a. Petitioner's Motion

In Petitioner's motion for a ruling on the record, filed on May 17, 2022, Petitioner argued that she is entitled to compensation. Pet'r's Mot. at 1. Petitioner asserted that the October 30, 2019 flu vaccine was a substantial factor in causing her injury and was a but-for cause of her injury. *Id.* at 19. Specifically, Petitioner asserted that her injury qualifies as a successful Table SIRVA claim and/or a causation-in-fact shoulder injury claim. *Id.*

Petitioner first addressed her Table SIRVA claim. *Id.* at 13. Petitioner stated that she had no history of pain, inflammation, or dysfunction in her right shoulder prior to vaccination. *Id.* at 13–14 (citing Pet'r's Ex. 4 at 5–114, 129). Next, Petitioner argued that her medical records and affidavit testimonies prove that her symptoms occurred within 48 hours of vaccination. *Id.* at 14–17 (citing Pet'r's Ex. 4 at 117–18, 124, 129–30, 145; Pet'r's Ex. 16 at ¶ 3; Pet'r's Ex. 17 at ¶ 3; Pet'r's Ex. 14 at ¶ 3; Pet'r's Ex. 15 at ¶ 2). Petitioner then stated that all of her reports of pain and symptoms were isolated to her right shoulder, as evidenced by the medical records. *Id.* at 17 (citing Pet'r's Ex. 4 at 130, 172). Finally, Petitioner argued that no other condition or abnormality would explain her right shoulder symptoms. *Id.* at 17–18.

Next, Petitioner addressed her causation-in-fact shoulder injury claim. *Id.* at 18. Petitioner asserted that the inclusion of SIRVA on the Table sufficiently establishes her burden under *Althen* prong one. *Id.* Next, Petitioner argued that the preponderant evidence satisfying the Qualifications and Aids in Interpretation ("QAI") criterion under Table SIRVA is sufficient to prove a logical sequence of cause and effect under *Althen* prong two. *Id.* at 18–19. Finally, Petitioner stated that the record establishes, by a preponderance of the evidence, that her right shoulder symptoms occurred immediately after the administration of the vaccine to sufficiently meet *Althen* prong three. *Id.* at 19.

Petitioner also included a discussion of damages, which is omitted as it is not relevant to this stage of Petitioner's claim. *Id.* at 20–24.

b. Respondent's Response

On July 7, 2022, Respondent filed a Rule 4(c) report which also served as Respondent's response to Petitioner's motion for a ruling on the record. Resp't's Report at 1. Respondent recommended against compensation for Petitioner's alleged injury. *Id.*

Respondent averred that Petitioner failed to meet her burden to establish a Table SIRVA claim for three reasons: (1) Petitioner did not establish by preponderant evidence that her right shoulder pain began within 48 hours of vaccination; (2) Petitioner's pain was not limited to her right shoulder; and (3) Petitioner has a history of neuropathic pain, cervical radiculopathy, and degenerative disc disease which all reflect alternative causes to explain Petitioner's symptoms. *Id.* at 8–9.

Respondent further argued that Petitioner failed to meet her burden to establish a causation-in-fact SIRVA claim because Petitioner has not established that she suffered a specific shoulder injury and lacked an expert report to articulate a medical theory in support of this claim. *Id.* at 9–10.

c. Petitioner's Reply

In Petitioner's reply, filed on July 13, 2022, Petitioner articulated four arguments in support of entitlement for her injury. Pet'r's Reply at 1–8. First, Petitioner responded to Respondent's critique that the medical records regarding onset were "vague[.]" *Id.* at 1. Petitioner averred that the medical records prove that Petitioner consistently reported pain since the vaccination and that numerous witness affidavits corroborate the immediate onset of symptoms. *Id.* at 1–2 (citing Pet'r's Ex. 4 at 117, 124, 129, 145; Pet'r's Ex. 14 at ¶ 3; Pet'r's Ex. 15 at ¶ 2; Pet'r's Ex. 16 at ¶ 3; Pet'r's Ex. 17 at ¶ 3).

Second, Petitioner stated that all reported pain was limited to her right shoulder, including symptoms of neck pain which were caused by her right shoulder injury. *Id.* at 4. Petitioner added that she was never diagnosed or treated for any cervical conditions. *Id.* at 5.

Third, Petitioner reiterated that she did not suffer from any other condition or abnormality that would explain her right shoulder symptoms. *Id.* at 5–6. Specifically, Petitioner responded to

Respondent's contention that the initial neuropathic pain and cervical radiculopathy diagnoses on December 19, 2019 can explain Petitioner's symptoms. *Id.* Instead, Petitioner argued that her complaints during that visit were solely musculoskeletal in nature and did not include neuropathic symptoms such as numbness or tingling. *Id.* at 6. Petitioner's subsequent visits and diagnosis reiterate that her injury was musculoskeletal in nature, ruling out alternate conditions or abnormalities to explain her right shoulder symptoms. *Id.* at 6–7.

Fourth, Petitioner reiterated that she has presented sufficient preponderant evidence to support a finding that her right shoulder injury was caused-in-fact by the flu vaccine at issue. *Id.* at 7. Petitioner argued that she has met all of the *Althen* prongs as required. *Id.* at 7–8.

IV. Applicable Legal Standard

The Vaccine Act provides petitioners with two avenues to receive compensation for their injuries resulting from vaccines or their administration. First, a petitioner may demonstrate that she suffered a "Table" injury-i.e., an injury listed on the Vaccine Injury Table that occurred within the provided time period. § 11(c)(1)(C)(i). "In such a case, causation is presumed." *Capizzano v. Sec'y of Health & Hum. Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006); § 13(a)(1)(B).

The Vaccine Injury Table lists a SIRVA as a compensable injury if it occurs within 48 hours of administration of a vaccination. § 14(a) as amended by 42 CFR § 100.3. Table injury cases are guided by statutory QAIs, which provide more detailed explanation of what should be considered when determining whether a petitioner has actually suffered an injury listed on the Vaccine Injury Table. *See* 42 CFR § 100.3(c). To be considered a "Table SIRVA," a petitioner must show that her injury fits within the following definition:

> SIRVA manifests as shoulder pain and limited range of motion occurring after the administration of a vaccine intended for intramuscular administration in the upper arm. These symptoms are thought to occur as a result of unintended injection of vaccine antigen or trauma from the needle into and around the underlying bursa of the shoulder resulting in an inflammatory reaction. SIRVA is caused by an injury to the musculoskeletal structures of the shoulder (e.g., tendons, ligaments, bursae, etc.). SIRVA is not a neurological injury and abnormalities on neurological examination or nerve conduction studies (NCS) and/or electromyographic (EMG) studies would not support SIRVA as a diagnosis . . .. A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following:
>
> (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection;
>
> (ii) Pain occurs within the specified time-frame;[31]

[31] Pain onset within 48 hours in a necessary condition for SIRVA injuries. 42 C.F.R. § 100.3(c)(10)(ii).

> (iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and
>
> (iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g., NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

42 CFR §100.3(c)(10).

Alternatively, if a petitioner is unable to establish a Table claim, she may bring an "off-Table" claim. § 11(c)(1)(C)(ii). An "off-Table," or causation-in-fact, claim requires that a petitioner "prove by a preponderance of the evidence that the vaccine at issue caused the injury." *Capizzano*, 440 F.3d at 1320; *see* § 13(a)(1)(A); *see* § 11(c)(1)(C)(ii)(II). A petitioner must show that the vaccine was "not only a but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly ex rel. Moberly v. Sec'y of Health & Hum. Servs.*, 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010) (quoting *Shyface v. Sec'y of Health & Hum. Servs.*, 165 F.3d 1344, 1352–53 (Fed. Cir. 1999)); *Pafford v. Sec'y of Health & Hum. Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006) (citations omitted).

In the seminal case of *Althen v. Sec'y of Health & Hum. Servs.*, the Federal Circuit set forth a three-pronged test to determine whether a petitioner has established a causal link between a vaccine and the claimed injury. *See* 418 F.3d at 1278–79. The *Althen* test requires petitioners to set forth: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." *Id.* at 1278. To establish entitlement to compensation under the Program, a petitioner is required to establish each of the three prongs of *Althen* by a preponderance of the evidence. *See id.*

Under the first prong of *Althen*, a petitioner must offer a scientific or medical theory that answers in the affirmative the question: "can the vaccine[] at issue cause the type of injury alleged?" *See Pafford v. Sec'y of Health & Hum. Servs.*, No. 01-0165V, 2004 WL 1717359, at *4 (Fed. Cl. Spec. Mstr. July 16, 2004), *mot. for rev. denied*, 64 Fed. Cl. 19 (2005), *aff'd*, 451 F.3d 1352 (Fed. Cir. 2006). To satisfy this prong, a petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Hum. Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). Such a theory must only be "legally probable, not medically or scientifically certain." *Id.* at 548–49. Petitioners are not required to identify "specific biological mechanisms" to establish causation, nor are they required to present "epidemiologic studies, rechallenge[] the presence of pathological markers or genetic disposition, or general acceptance in the scientific or medical communities." *Capizzano*, 440 F.3d at 1325 (quoting *Althen*, 418 F.3d at 1280). Scientific and "objective confirmation" of the medical theory with additional medical documentation is also unnecessary. *Althen*, 418 F.3d at 1278–81; *Moberly*, 592 F.3d at 1322. However, as the Federal Circuit has made clear, "simply identifying a 'plausible' theory of causation is insufficient for a petitioner to meet her burden of proof." *LaLonde v. Sec'y of Health & Hum. Servs.*, 746 F.3d 1334, 1339 (Fed. Cir. 2014) (citing *Moberly*, 592 F.3d at 1322). Rather, "[a] petitioner must provide a reputable medical or scientific explanation that pertains specifically to the petitioner's case." *Moberly*, 592 F.3d at 1322. In general, "the statutory standard of

preponderance of the evidence requires a petitioner to demonstrate that the vaccine more likely than not caused the condition alleged." *LaLonde*, 746 F.3d at 1339.

Furthermore, establishing a sound and reliable medical theory connecting the vaccine to the injury often requires a petitioner to present expert testimony in support of her claim. *Lampe v. Sec'y of Health & Hum. Servs.*, 219 F.3d 1357, 1361 (Fed. Cir. 2000). The Supreme Court's opinion in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), requires that courts determine the reliability of an expert opinion before it may be considered as evidence. "In short, the requirement that an expert's testimony pertain to 'scientific knowledge' establishes a standard of evidentiary reliability." *Id*. at 590 (citation omitted). Thus, for Vaccine Act claims, a "special master is entitled to require some indicia of reliability to support the assertion of the expert witness." *Moberly*, 592 F.3d at 1324. The *Daubert* factors are used in the *weighing* of the reliability of scientific evidence proffered. *Davis v. Sec'y of Health & Hum. Servs.*, 94 Fed. Cl. 53, 66–67 (2010) ("[U]niquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted."). Nothing requires the acceptance of an expert's conclusion "connected to existing data only by the *ipse dixit* of the expert," especially if "there is simply too great an analytical gap between the data and the opinion proffered." *Snyder v. Sec'y of Health & Hum. Servs.*, 88 Fed. Cl. 706, 743 (2009) (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)).

Under the second prong of *Althen*, a petitioner must prove that the vaccine actually did cause the alleged injury in a particular case. *See* 418 F.3d at 1279. The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Id.* at 1278; *Capizzano*, 440 F.3d at 1326; *Grant v. Sec'y of Health & Hum. Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). A petitioner does not meet this obligation by showing only a temporal association between the vaccination and the injury; instead, the petitioner "must explain *how* and *why* the injury occurred." *Pafford*, 2004 WL 1717359, at *4 (emphasis in original). The special master in *Pafford* noted petitioners "must prove [ ] both that [the] vaccinations were a substantial factor in causing the illness . . . and that the harm would not have occurred in the absence of the vaccination." *Id.* (citing *Shyface*, 165 F.3d at 1352). A reputable medical or scientific explanation must support this logical sequence of cause and effect. *Hodges v. Sec'y of Health & Hum. Servs.,* 9 F.3d 958, 961 (Fed Cir. 1993) (citation omitted). Nevertheless, "[r]equiring epidemiologic studies . . . or general acceptance in the scientific or medical communities . . . impermissibly raises a claimant's burden under the Vaccine Act and hinders the system created by Congress . . .." *Capizzano*, 440 F.3d at 1325-26. "[C]lose calls regarding causation are resolved in favor of injured claimants." *Althen*, 418 F.3d at 1280.

In Program cases, contemporaneous medical records and the opinions of treating physicians are favored. *Capizzano*, 440 F.3d at 1326 (citing *Althen*, 418 F.3d at 1280). Indeed, when reviewing the record, a special master must consider the opinions of treating physicians. *Id.* This is because "treating physicians are likely to be in the best position to determine whether 'a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury.'" *Id.* (quoting *Althen*, 418 F.3d at 1280). In addition, "[m]edical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally

contemporaneous to the medical events." *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993). While a special master must consider these opinions and records, they are not "binding on the special master or court." § 13(b)(1). Rather, when "evaluating the weight to be afforded to any such . . . [evidence], the special master . . . shall consider the entire record . . . ." *Id.*

To satisfy the third *Althen* prong, a petitioner must establish a "proximate temporal relationship" between the vaccination and the alleged injury. *Althen*, 418 F.3d at 1281. This "requires preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact." *de Bazan v. Sec'y of Health & Hum. Servs.,* 539 F.3d 1347, 1352 (Fed. Cir. 2008). Typically, "a petitioner's failure to satisfy the proximate temporal relationship prong is due to the fact that onset was too late after the administration of a vaccine for the vaccine to be the cause." *Id.* However, "cases in which onset is too soon" also fail this prong; "in either case, the temporal relationship is not such that it is medically acceptable to conclude that the vaccination and the injury are causally linked." *Id.*; *see also Locane v. Sec'y of Health & Hum. Servs.*, 685 F.3d 1375, 1381 (Fed. Cir. 2012) ("[If] the illness was present before the vaccine was administered, logically, the vaccine could not have caused the illness.").

Although a temporal association alone is insufficient to establish causation, under the third prong of *Althen*, a petitioner must show that the timing of the injury fits with the causal theory. *See Althen*, 418 F.3d at 1278. The special master cannot infer causation from temporal proximity alone. *See Thibaudeau v. Sec'y of Health & Hum. Servs.*, 24 Cl. Ct. 400, 403-04 (1991); *see also Grant*, 956 F.2d at 1148 ("[T]he inoculation is not the cause of every event that occurs within the ten[-]day period . . . [w]ithout more, this proximate temporal relationship will not support a finding of causation." (quoting *Hasler v. United States*, 718 F.2d 202, 205 (6th Cir. 1983))).

Once a petitioner has established her prima facie case, the burden then shifts to Respondent to prove, also by preponderant evidence, that the alleged injury was caused by a factor unrelated to vaccination. *Althen*, 418 F.3d at 1278 (citations omitted); § 13(a)(1)(B). The Vaccine Act requires Respondent to establish that the factor unrelated to the vaccination is the more likely or principal cause of the injury alleged. *Deribeaux v. Sec'y of Health & Hum. Servs.*, 717 F.3d 1363, 1369 (Fed. Cir. 2013). Such a showing establishes that the factor unrelated, not the vaccination, was "principally responsible" for the injury. *See* § 13(a)(2)(B). The factor unrelated must be the "sole substantial factor[;]" therefore, Respondent must establish that the factor unrelated, not the vaccination, actually caused the injury alleged. *See de Bazan*, 539 F.3d at 1354.

V. Analysis

As a preliminary matter, the parties in this case disagree on the nature of Petitioner's injury, even as they both identify adhesive capsulitis as the likely diagnosis. Petitioner presented to her primary care physician on November 20, 2019, twenty-one days post vaccination, with complaints of neck pain and spasms. Petitioner's symptoms continued to evolve, and during an examination conducted on December 10, 2019, she complained of decreased mobility, sharp pain, and right shoulder tenderness. Petitioner contended that she suffers from a SIRVA: a medical condition listed on the Program's Vaccine Injury Table that is further defined by legal factors known as

QAIs. Respondent's expert, Dr. Abrams, argued that although Petitioner's symptoms may suggest SIRVA, her presentation does not satisfy the QAI criteria because of reported neck pain.

Petitioner's expert, Dr. Bodor, explained how Petitioner's complaint of neck pain is consistent with SIRVA. He persuasively argued that given the location of the trapezius muscle, pain in this area is often associated with the neck and is "frequently experienced in conjunction with shoulder problems" due to "overuse secondary to increased rotation of the scapula to compensate for reduced movement at the glenohumeral joint." Pet'r's Ex. 19 at 5. However, this complaint of neck pain is inconsistent with the third Table criterion that pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered.

Additionally, a Table claim is often precluded in cases where another condition or abnormality is present that would explain the symptoms, e.g., clinical evidence of radiculopathy or any other neuropathy. Dr. Bodor acknowledged that radiculopathy was listed as a potential diagnosis for Petitioner. Indeed, neuropathy was considered as a potential differential diagnosis early on, but Dr. Bodor addressed Petitioner's possible radiculopathy diagnosis by noting that Petitioner lacked any numbness or tingling symptoms consistent with a neuropathy. Additionally, she was never diagnosed with a neuropathy by a specialist. Moreover, Dr. Abrams did not assert that Petitioner suffered from a neuropathy.

Dr. Abrams also did not suggest there was another cause of Petitioner's shoulder pain, but he argued that her injury is unrelated to vaccination. He asserted that "adhesive capsulitis that arises outside of any SIRVA event is one of the most common causes of shoulder pain in middle-aged females." Resp't's Ex. A at 5. However, this is insufficient to establish that there is another condition or abnormality to explain Petitioner's symptoms. "[T]he proposed rulemaking defining SIRVA specifically includes adhesive capsulitis as a condition falling within the scope of SIRVA." *O'Leary v. Sec'y of Health & Hum. Servs.*, No. 18-584V, 2021 WL 3046617, at *11 (Fed. Cl. Spec. Mstr. June 24, 2021) (citing Proposed Rulemaking, 2015 WL 4538923, at *45136). In this case, Dr. Bodor and Dr. Abrams both opined that Petitioner could have developed adhesive capsulitis. The medical records and the opinions of both parties' experts amount to preponderant evidence that Petitioner suffered from adhesive capsulitis.

In summary, while the medical record reveals that there was ultimately no evidence of neuropathy,[32] Petitioner's characterization of her injury to include neck pain is not limited to her shoulder and therefore does not satisfy the third Table criterion. Because a petitioner is only considered to have suffered a Table SIRVA injury if all of the criteria are met, Petitioner's Table claim must fail. *See* 42 C.F.R § 100.3(c)(10).

While a Table SIRVA claim is one basis for entitlement, it is also a very limited condition with strict parameters to facilitate easy identification and settlement. Non-Table shoulder injuries can also be the basis for a successful claim in the Program, but the petitioner must prove causation where it would otherwise be presumed. Non-Table shoulder injuries often include symptoms that overlap with those seen in a Table SIRVA, including adhesive capsulitis.

[32] There is also no evidence of a prior condition and I find pain onset is within 48 hours, as discussed more below. Therefore, Petitioner satisfies the first, second, and fourth Table criteria.

Although Petitioner is unable to prevail on a Table claim, she can still succeed on her alternative theory that she suffered a shoulder injury caused-in-fact by her vaccination. Petitioner alleged that she suffered a shoulder injury that is commonly seen in the Program, adhesive capsulitis. However, for Petitioner's non-Table claim, she must still provide a sound and reliable medical theory of causation and a logical sequence of cause and effect in her case.

I find that Petitioner presented a scientific or medical theory that explains how an improperly administered flu vaccine can cause a shoulder injury that initiates a localized immune response and develops into soreness, stiffness, and ultimately frozen shoulder or adhesive capsulitis. Dr. Bodor described Petitioner's clinical presentation as a chain reaction that started as a "focal autoimmune response, consisting of progressively increasing inflammation and eventually adhesive capsulitis." Pet'r's Ex. 16 at 2. He referenced Petitioner's complaints to treaters and her statements filed in this case as evidence of a localized immune response. Dr. Abrams argued Petitioner's symptoms manifested too late following her vaccination, and that she did not have edema or other evidence of an inflammatory response to indicate that the vaccine needle was inappropriately placed in Petitioner's arm.

While it is true Petitioner did not seek medical care in the days immediately following her vaccination, she consistently reported that the pain began following her flu shot. Petitioner described how she attempted to self-treat her pain, even as it worsened, and she exhibited evidence of limited range of motion upon later examination. Petitioner provided statements from several witnesses, including her spouse, coaches, and friends, corroborating her statement that pain immediately followed her vaccination and limited her range of motion. Petitioner has presented preponderant evidence that her shoulder pain manifested immediately after vaccination. She detailed her efforts at self-care and then sought treatment as her pain worsened and she needed physical therapy and surgery. Petitioner's medical records note that she was prescribed topical cream to treat localized pain, stiffness, and spasms post-vaccination. Dr. Abrams' assertion that Petitioner's pain onset is untimely with respect to her vaccination because she did not immediately see a medical professional is not sufficient to overcome the other evidence.

Dr. Bodor also referred to Petitioner's description of the pain in her arm at the time of vaccination to argue the pain was immediate and beyond the scope of a common vaccination reaction. I find that Petitioner has presented preponderant evident that her injury occurred immediately following her vaccination, consistent with an injury suffered as a result of improper administration. Dr. Bodor continued with the medical record account of Petitioner's gradual development of frozen shoulder and the discovery of a rotator cuff tear, requiring multiple rounds of physical therapy and surgeries. Dr. Bodor argued that this clinical progression is analogous to what you would see in a SIRVA case in terms of onset, severity, and duration. I find this line of reasoning persuasive. Dr. Abrams did not dispute the nature and progression of Petitioner's injury. He did not persuasively argue that her presentation was inconsistent with a vaccine-caused shoulder injury.

Therefore, I find that Petitioner has presented a scientific or medical theory, satisfying the first *Althen* prong. *See Althen*, 418 F.3d at 1278. Petitioner's medical records contain preponderant evidence that following her vaccination, she experienced symptoms consistent with her theory, thus, satisfying the second *Althen* prong. *Id.* Lastly, Petitioner's statements provide preponderant

evidence that the onset of her right shoulder pain occurred on October 30, 2019, within 48 hours of vaccination. The timing of onset shows a proximate temporal relationship that is appropriate given the mechanism of injury. Thus, Petitioner has satisfied the third *Althen* prong. *Id.*

VI. Conclusion

After careful review of the record, Petitioner has established by preponderant evidence that she suffered from a shoulder injury in her right shoulder that was caused-in-fact by her October 20, 2019 flu vaccination. Accordingly, Petitioner is entitled to compensation. This case shall proceed to damages.

IT IS SO ORDERED.

/s/ Herbrina D. Sanders
Herbrina D. Sanders
Special Master